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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|---------------------------|---------------------|------------------|
| 09/233,443      | 01/20/1999  | BERNHARD H. VAN LENGERICH | BVL-105             | 7428             |

7590            04/21/2004

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[REDACTED] EXAMINER

WEBMAN, EDWARD J

[REDACTED] ART UNIT    [REDACTED] PAPER NUMBER  
1617

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|--------------------|-------------|-----------------------|------------------|

09/233 443

EXAMINER

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| ART UNIT | PAPER NUMBER |
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3/19/04

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on 12/31/03
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- Claim(s) 21, 22, 26, 29, 47-55, 60, 67, 96-115 is/are pending in the application.  
Of the above, claim(s) 53, 98, 100 is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 21, 22, 26, 29, 47-52, 55, 66, 67, 96, 97, 99, 101-109 is/are rejected.
- Claim(s) 54, 57, 110-115 is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 22, 26, 29, 47-52, 55, 66-67, 96, 97, 99, 101-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagesna et al in view of Cavalier Vesely et al, Hampton et al and Craig et al.

Vagesna et al teach non-baked Granules comprising cholestyramine, oil, and a grain or flour (abstract). 10-15% oil is disclosed (column 2 lines 65-66). 15-17% water is specified (column 6 lines 9-11). Control of high cholesterol levels is specified (column 1 lines 10-13). A substantially homogenous mixture is disclosed (column 6 lines 15-18). Wheat is specified (column 3 lines 28-31). Tablets are disclosed (abstract).

Cavaliere Vesely teaches lactobacilli for the treatment of hypercholesterolemia (abstract). Pellets and tablets are specified (column 3 lines 19-22). 10-95% is disclosed (column 2 lines 30-34).

It would have been obvious to one of ordinary skill to add lactobacilli to the composition of Vagesna et al to achieve the additional beneficial effect of a second agent for treating high cholesterol in view of Cavaliere Vesely et al. As to the claimed durum wheat, gluten is a well-known binder for tablets (Hampton et al column 1 lines 57-58) and durum wheat is well known as high in gluten content (Craig et al column 1 lines 31-34). Thus, it would be an obvious expedient to choose durum for the Vagesna et al wheat to achieve the beneficial effect of the tablet binding property of gluten

contained therein. As to the claimed controlled release, such a limitation is merely an intended use. As to the claimed process of making, such is not considered a patentable limitation during prosecution of product claims before the USPTO.

Applicant argues there is no motivation to combine. However, said motivation is provided. Craig is cited only for its teaching regarding gluten content.

Claims 21, 22, 26, 29, 47-52, 55, 66-67, 96, 97, 99, 101-109 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.

Webman/tgd

March 23, 2004

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500